K111145

Medacta International

AUG 16 2011

510(k) Summary

Manufacturer: Medacta International SA
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Date Prepared: April 19th, 2011

DEVICE INFORMATION

Trade/Proprietary Name: Endo Head
Common Name: Unipolar Head
Classification Name: prosthesis, hip, hemi-, femoral, metal ball

21 CFR 888.3360
Class II
Device Product Codes: LZY

Predicate Devices: K896580 - Smith & Nephew Unipolar System
K062408 - Smith & Nephew Modular Femoral (Hemi) Heads
K072857 - Medacta CoCrMo Femoral Ball Heads, 28 and 32mm
K080885 - Medacta CoCrMo Femoral Ball Heads, 22 and 36mm
K103721 - Medacta CoCrMo Femoral Ball Heads, 40mm

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Product Description

The Medacta Endo Head is a unipolar prosthesis that consists of a monobloc prosthetic femoral head made of Cobalt Chromium Molybdenum (CoCrMo ISO 5832-12) designed to articulate directly in the patient's acetabulum. It is designed to be assembled with all the Medacta stems. Three sizes (S, M and L) are available for a 12/14 Morse taper with an outer diameter varying from 40 to 56 mm with 1 mm increments between sizes.

Indications for Use

The Medacta Endo Head is intended for use in combination with Medacta Hip Prosthesis System for primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:
• Femoral neck and trochanteric fractures of the proximal femur;
• Osteonecrosis of the femoral head;
• Revision procedures where other devices or treatments for these indications have failed.

Comparison to Predicate Devices

The Endo Head has the same intended use, material, neck lengths, and external diameter size range as the previously cleared Unipolar System manufactured by Smith and Nephew (K896580). The Endo Head's material, sterilization, biocompatibility, and coupling with the Medacta stems is substantially equivalent to the Medacta CoCr Femoral Heads cleared under K072857, K080885, and K103721.

Conclusion:
Based on the above information, the Endo Head can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medacta International
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Mr. Adam Gross
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Camarillo, California 91302

AUG 16 2011

Re: K111145
Trade/Device Name: Endo Head
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: LZY
Dated: July 28, 2011
Received: July 29, 2011

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

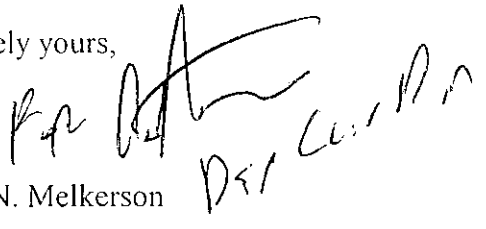
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111145

Device Name: Endo Head

Indications For Use:

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Prescription Use ____x___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111145